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Hazard Evaluation Division
Standard Evaluation Procedure
Non-Target Plants
Target Area Testing

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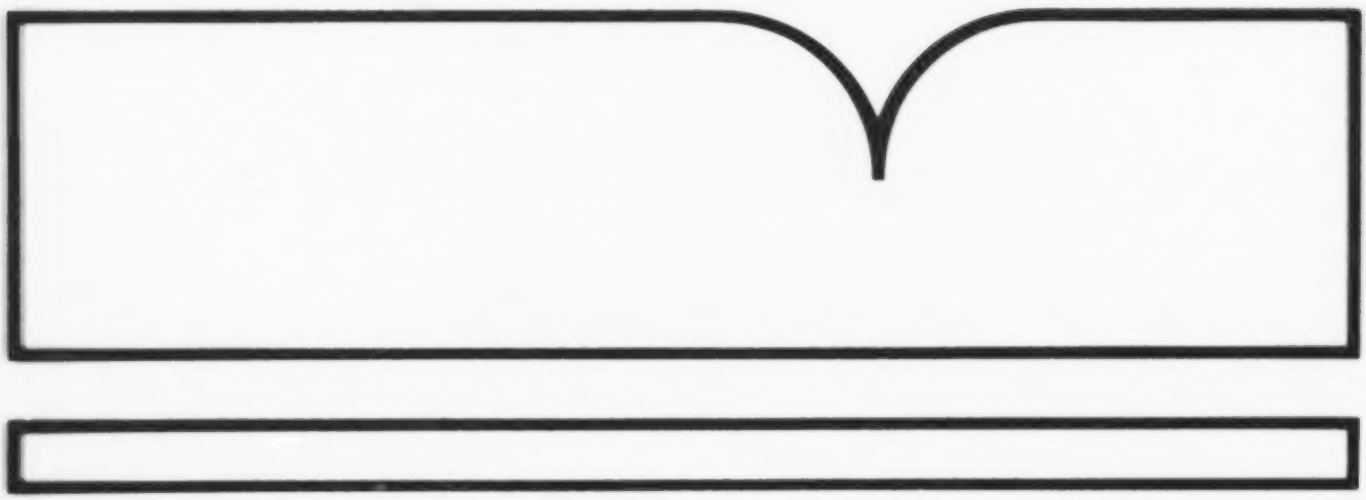

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HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

NON-TARGET PLANTS:

TARGET AREA TESTING

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The Standard Evaluation Procedure for Non Target Plants: Target Area Testing, a Federal Insecticide, Fungicide and Rodenticide (FIFRA) Standard Evaluation Procedure (SEP), prescribes the evaluation criteria and procedures to assess this pesticide phytotoxicity study that the US Environmental Protection Agency recommends to support the registration of manufacturing-use and formulated end-use products. This SEP, in conjunction with the Pesticide Assessment Guidelines, Subdivision J. is designed to aid data reviewers in their evaluation of target area testing studies submitted by registrants. A summary of the rulemaking phytotoxicity test requirements can be found in 40 CFR Part 158. The study results contained in the evaluation procedure together with environmental fate and efficacy data are used to assess the potential hazard of pesticides to terrestrial and aquatic nontarget plants.

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NON-TARGET PLANTS: TARGET AREA TESTING

I. INTRODUCTION

A. Purpose of the Standard Evaluation Procedure

This Standard Evaluation Procedure is designed to aid Ecological Effects Branch (EEB) data reviewers in their evaluations of greenhouse/field plot target area testing studies submitted by registrants in the assessment of pesticide effects on desirable plants within the target area.

B. Background Information

Target area testing studies are designed to provide phytotoxicity information on a pesticide. These phytotoxicity data are needed to evaluate the effect of the level of pesticide exposure to target area terrestrial and aquatic plants that are not intended to be controlled, and to assess the impact of pesticides on endangered and threatened plants as noted under the Endangered Species Act. Where a phytotoxic effect is noted in one or more plant species, further target area phytotoxicity studies may be required (after consultation with the Agency). These studies are required by 40 CFR § 158.150 to support the registration of any pesticide intended for outdoor use under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.

The target area phytotoxicity studies are unique because the pesticide is being applied directly to the plant. In addition to the direct application, several factors can affect the degree of possible phytotoxic response. Cultural practices can vary with production areas and frequently from grower to grower within an area. These include irrigation practices, mowing, and field cultivation practices. Method of application can dictate the route of exposure of the pesticide to the plant, i.e., whether it is by the roots or shoots and leaves. Spray versus furrow chemigation can also dictate the degree of exposure and resultant phytotoxicity.

Pesticides with outdoor use patterns that do not readily release the pesticide to the environment will have to be evaluated using this phytotoxicity test. These use patterns include subsurface soil applications, recapture systems, wick applications and swimming pool uses. Those uses that include long-term or total vegetation control, e.g., clean yard chemicals, desiccants and defoliants, need not be evaluated.

C. Objective of the Target Area Test

The objective of the target area test is to determine if a pesticide exerts any detrimental effects to plants during the exposed growth period of their development. The test is performed on those desirable target area or pest host plant species as listed on the label which will be in the target area. Being a multiple dose test, it is designed to evaluate the phytotoxic effects of the pesticide over a wide range of anticipated pesticide quantities as may be found in the environment.

II. INFORMATION TO BE SUPPLIED

The registrant's report on target area testing studies should include all information necessary to provide: 1) a complete and accurate description of the greenhouse/field plot treatments and procedures, 2) sampling data and phytotoxicity rating, 3) data on storage of the plant material until analysis, if so performed, 4) any chemical analysis of the plant material as to chemical content, if so performed, 5) reporting of the data, rating system and statistical analysis, and 6) quality control measures/precautions taken to ensure the fidelity of the operations.

A guideline of specific information that should be included in the registrant's report of target area testing studies is provided in Appendix 1 of this document. The lists of required information and reviewer aids are derived from the Pesticide Assessment Guidelines, Subdivision J: Hazard Evaluation of Non-Target Plants, which is complemented by this Standard Evaluation Procedure.

III. DATA INTERPRETATION

The acceptability of the study results will depend upon whether the test requirements/standards are followed. If a deviation is made, a determination must be made as to whether the deviation has changed the quality of the results in such a manner that the results cannot be extrapolated to the natural environment. There should be little or no deviation from the liberalized standards prescribed in this study.

The results of the phytotoxicity tests of the chemical with respect to the quantity applied to the plant as a whole, whether to the foliage, fruit or soil, are important. The concentration of the chemical in the carrier is important in that stronger concentrations than normally used can lead to burning and necrosis. Subtoxic concentrations, on the other hand, may cause unwanted rapid growth.

Plants can recover from certain types of injury that will have little or no effect on the esthetic or economic value of the plant(s) tested or on which an evaluation is made. Therefore, it is important that a minimum of two weeks of observations be made after the last application of the pesticide, preferably three to four weeks, to note any detrimental effects.

There is no decision point for this test as to whether additional target area/non-target plant studies must be performed.

IV. THE DATA EVALUATION PROCESS

Upon careful examination of the information/data supplied by the registrant in his submission to the Agency, the reviewer shall evaluate the data as follows.

A. Identify Data Gaps

Using Appendix 1 of this document as a guide, the reviewer should look for data gaps - omissions in the information supplied by the registrant in his report. These should be duly noted in the reviewer's report, and a judgment made as to which are considered significant enough to adversely affect the review process. Those so identified should be communicated back to the registrant by the Product Manager for corrective action.

B. Assess the Appropriateness and Adequacy of the Data

The data reviewer then considers the appropriateness, i.e., the intended use pattern, and adequacy of the data/information that has been supplied. Appendix 1 of this document is a useful guide to the various parameters that need to be considered. Appendix 2 provides specific questions that should be answered by the reviewer during the study evaluation process. Statistical treatments of the data should be independently verified and the quality control precautions noted.

As an adjunct to these, the reviewer should draw upon the technical guidance in the reviewer aids materials that are available. (See also the recommended references in Subdivision J - Hazard Evaluation: Non-Target Plants.) A listing of additional source materials is located in the references section of this document.

In addition to the data gaps noted above, any perceived deficiencies in the data/information supplied should also be identified. A statement as to these deficiencies should be made in the reviewer's report and corrective action to resolve them should be provided. This information can be relayed to the registrant by the Product Manager for appropriate action.

C. Report Preparation

The Agency reviewer prepares a standard review report following the standard format for preparation of scientific reviews as provided in Appendix 3 of this document. All important information provided by the registrant including the methodology and results is to be summarized in order that future evaluations can be made. The results may be expressed in the form of tables where specific values are related. Figures (graphs) may be provided but are not to be the sole source of the values needed for future evaluations.

D. Conclude if the Requested Action is Supportable

Lastly, the reviewer considers the results of the terrestrial field testing studies and makes a judgment as to whether they support the requested registration action of the data submitter. If the data are not supportive, possible alternative action(s) that may be taken by the registrant, such as label modifications, are suggested. If deficiencies/omissions exist in the submitted data, the reviewer may have to defer judgment until such time as appropriate corrective action has been rendered by the registrant.

APPENDIX 1

INFORMATION REQUESTED OF THE REGISTRANT

The registrant's report on target area testing studies should include all information necessary to provide: 1) a complete and accurate description of the greenhouse/field plot treatments and procedures, 2) sampling data and phytotoxicity rating, 3) data on storage of the plant material, if so performed, 4) any chemical analysis of the plant material as to chemical content, if so performed, 5) reporting of the data, rating system and statistical analysis, and 6) quality control measures/precautions taken to ensure the fidelity of the operations.

Specifically, each greenhouse/field plot target area testing report should include the following information.

I. General

° Cooperator or researcher (name and address), test location (county and state; country, if outside of the U.S.A.), and date of study;

° Name (and signature), title, organization, address, and telephone number of the person(s) responsible for planning/supervising/monitoring and, for field plot studies, applying the pesticide;

° Trial identification number;

° Quality assurance indicating: control measures/precautions followed to ensure the fidelity of the phytotoxicity determinations; record-keeping procedures and availability of logbooks; skill of the laboratory personnel; equipment status of the laboratory and/or greenhouse; degree of adherence to good laboratory practices; and degree of adherence to good agricultural practices in maintaining healthly plants; and

° Other information the registrant considers appropriate and relevant to provide a complete and thorough description of the test procedures and results.

II. Test Substance (Pesticide)

° Identification of the test pesticide active ingredient (ai) including chemical name, common name (ANSI, BSI, ISO, WSSA), and Company developmental/experimental name;

° Active ingredient percentage in the end-use product or representative end-use product. The representative end-use product shall

be of the same active ingredient and formulation category, but it may be of a different concentration, i.e., 2% wettable powder vs. 4% wettable powder;

° Additional solvents or adjuvants used to dissolve and apply the pesticide if the pesticide is intended for use at aquatic sites and it is insoluble in or immiscible with water;

° Dose rate(s) in terms of active ingredient per area of land, water, or leaf (if leaf-area-index is provided);

° Dose rate(s) in terms of minimum, maximum (or greatest allowable concentration) and two times the maximum label application level rate and with an estimated non-discernible effect (or no-effect) level;

° Method of application including equipment type, nozzles, pressure, etc.; and

° Number of applications.

III. Plant Species

° Identification of the desirable target area or pest host plant species with family identification. Scientific and common names shall be provided;

° Identification of the number of replicates and the number of plants per replicate per dose; and

° Identification of the date of planting, date(s) of pesticide application, and date(s) of phytotoxicity rating or harvest.

IV. Site of the Test

° Site description of the target area testing study such as whether it was performed in a greenhouse, field plot, forest, or aquatic site;

° Location of the test site, geographically;

° Climatological data during the test (records of applicable conditions for the type of site, i.e., temperature, thermoperiod, rainfall or water regime, photoperiod, light intensity and quality, relative humidity, wind speed, etc.);

° Field lay-out (for field plots), e.g., size and number of control and experimental plots; number of plants per plot/unit area;

° Pot (greenhouse only) or row density of terrestrial plants (or their seeds);

° The intended use pattern(s) as noted on the label for which the test(s) is (are) being performed;

° Cultural practices such as cultivation and irrigation; and

° Substrate characteristics (terrestrial uses, including forests: name/designation of soil type and its physical and chemical properties including pH and percent organic matter, soil moisture content; aquatic uses: water body type, water chemistry including pH, hardness, CEC, suspended sediments, benthic conditions).

V. Results

° Target area plant responses, including detrimental effects on crops, commodities (produce), or any other desirable plant species, such as stand, vigor, planting depths, lodging, phytotoxicity (including a description of the rating system), and yields, to ascertain toxic effects of the pesticide upon the plants;

° Statistical analysis of the results; and

° Other evaluations for the individual use pattern(s) and application methodology, and cultural practices as indicated in Section 121-1 (c) of Subdivision J.

APPENDIX 2

SPECIFIC QUESTIONS FOR THE REVIEWER

The following questions are provided to aid the reviewer in performing the standard evaluation procedure in a scientific manner and in acquiring the necessary information to complete the standard format for preparation of scientific reviews.

I. General

° Were the name of the cooperator or researcher (name and address), test location (county and state; country, if outside of the U.S.A.), and date of study provided?

° Were the name (and signature), title, organization, address, and telephone number of the person(s) responsible for planning/supervising/monitoring and, for greenhouse and/or small field plot studies, applying the pesticide provided?

° Was the trial identification number provided?

° Were quality assurance control measures/precautions indicated?

II. Test Chemical

° Was the test chemical used the end-use product or a representative end-use product of a similar formulation, i.e., wettable powder, liquid, emulsifiable concentrate, etc.?

° Was the active ingredient percentage of the chemical given?

° Were the doses given in quantity per unit area (of plant or land or water surface)?

° Were the doses the minimum, maximum (or greatest allowable concentration), and two times the maximum label application level or rate?

° Was an estimated non-discernible effect (or no-effect) level tested?

° If an adjuvant was allowed or recommended on the label, was it also tested at the maximum rate in conjunction with the intended pesticide product?

° Where tank mixtures are recommended, were such tank mixtures required and tested?

° Where serial applications of pesticides are recommended on the label, were such applications made and evaluated?

III. Test Species

° Were the test species the desirable target area or pest host plant species as listed on the label?

° Where various cultivars could be used, such as in the case of most agronomic and horticultural plants, were cultivar or varietal names and sources provided, where available?

° Were the scientific names provided?

° Were the cultivars or varieties representative of those that would most likely be used?

° Were the plants in the stage(s) of growth development during which the pesticide would be applied as according to the label?

° Were the plants healthy and not in a state of stress?

° Were endangered or threatened plant species not used?

IV. Test Procedures

° Was the test site specified, i.e., greenhouse or small field plot?

° Were the environmental conditions that prevailed during the test (temperature, thermoperiod, light regime - intensity and quality, rainfall or watering regime, relative humidity, wind speed, etc.) provided as appropriate for the site?

° Were the environmental conditions that prevailed during the test those that would normally prevail during the application of the pesticide as labeled?

° Was the test duration at least two weeks in length or until either severe detrimental effects or sustained recovery had occurred?

° Were observations taken at least weekly?

° Was the method of pesticide application as indicated on the label, i.e., aerial, irrigation, directed sprays (hydraulic ground-rig), mist blowers, subsurface, and aquatic systems other than irrigation, evaluated and the type of application equipment use reported? Specific detail as to descriptions of equipment design, adjustment, and operation should be provided involving aerial applications and applications using conventional farm equipment (such as tillage or planting equipment), irrigation systems, mechanical

incorporation, directed sprays, mist blower (air blast, air carrier), subsurface placement, or band rather than broadcast distribution?

° Were sufficient untreated controls or checks provided?

° Did the untreated controls receive the same treatment, i.e., fertilization, pesticide treatments and cultivation, with the exception of the pesticide in question, as did the treated plants?

V. Reporting

° Were the detrimental effects reported for the following use patterns as indicated?

- Use in field crops. Were the effects of pesticides on desirable target area plants evaluated and reported? Were the extent and duration of the effect expressed in terms of stand and vigor, recovery, yields and degree of phytotoxicity?

- Use on pastures and rangelands. Were the effects of pesticides on desirable target area plants evaluated and reported? Were the severity and duration of adverse effects on desirable plant species expressed in terms of stand and vigor reductions, recovery, and changes in yields? Were data submitted addressing reseeding intervals which minimize adverse effects on reseeded plants, and animal grazing recommendations which allow recovery of desired plant species? If the applied pesticide kills all vegetation in the treated area for an extended period of time resulting in bare spots, did the registrant record the duration of this effect, estimated soil loss by erosion and any changes in vegetation cover (desirable or undesirable)?

- Use on and around fruit and nut trees. Where applications of pesticides were made on and/or around fruit and nut trees, were evaluations and reports made of the detrimental effects on foliage, and changes in growth compared to preapplication measurements and simultaneous controls? Were reports made of pesticide applications to bearing fruit and nut tree areas with reporting of detrimental effects on yields and commodity (produce) quality for the year of and the year after application? Were supporting data provided addressing, for all trees, the age of the trees, the transplant-to-application interval, and the maximum allowable extent of contact between the pesticide (with particular reference to herbicide spray drift) and trees? For ground sprays, unless the pesticide is broadcast over the entire orchard floor, were the method of the application (band, spot, shielded, or directed spray application) and the size of the treated ground area around the tree trunk indicated? Were assessments of root sucker treatments made, where applicable? For foliar sprays, did the data include the volume of finished spray applied per unit of land area, concentration of product in the spray solution, and the extent of foliage coverage (such as volume of finished spray per tree or application to the point of runoff)?

- Use on lawns and turf. Did the evaluation of effects of pesticides on representative species or cultivars of desirable lawn and turf plants include such factors as color, density, percent cover, growth rate, rooting, and tillering? If use on bentgrass is intended, was this highly susceptible species evaluated? Did the data address use on newly-seeded lawns by demonstrating safety to representative species and cultivars of desirable lawn plants to be named on the label as kinds on which the product is safe to use, with seeding-to-application intervals (if appropriate)? Did the data also address use of an appropriate application-to-reseeding interval for each of these desirable lawn plants that may be reseeded? Where interactions between herbicide application and lawn cultural practices can occur such as with raking, mowing, mowing height, watering, and fertilizing, were they evaluated for possible adverse effects on desirable lawn species? In situations where fertilizer and a pesticide are applied serially and both types of products may contact the emerged crop foliage (such as in turf or lawns), was the interval between application of the pesticide and the fertilizer reported, as well as any resultant phytotoxic effect, stunting, or discoloration, and recovery time for the injured desirable species?

- Use around ornamentals. Was an evaluation of the sensitivity of representative cultivars of the desirable ornamental species included? Was the method of application identified as to directed spray and/or topical applications? Were the growth stage of the ornamentals and the transplant-to-application interval (when applicable) indicated in the test report? Was information submitted on specialized nursery cultural practices employed in tests, such as use of artificial soils, mulches, containerized stock, and other pesticides?

- Use in forest management. Were the effects of the pesticide on desirable plant species commonly present in forest management, in addition to the desirable forest trees, indicated in the report with any detrimental or adverse effects that the pesticide may cause? Was special attention given to pesticidal effects on noncompetitive ground cover species that aid in the land management practices such as erosion control? Were appropriate testing and assessment techniques adapted to the size of the plot to determine the effect of pesticides on all plants?

- Aquatic applications. When a pesticide is applied to a natural aquatic system or flood or furrow irrigation system, was the following application information included, where applicable (Note: overhead and/or sprinkler irrigation system applications shall follow the specific use patterns given above):

(1) Target site where the pesticide was applied (for example, to weed foliage, to surface of water, to bottom of water body, into water, to ditchbank, to shoreline, or to forests);

(2) Description of any water level changes used in conjunction with the pesticide application, such as drawdown operation

or drainage ot conveyance system, including the extent of water level change, the time of the change in relation to the pesticide application, and the duration of the change in water level; and

(3) The date of the application in relation to the stage of growth of the target and non-target organisms.

° Were the detrimental effects on crops, commodities (produce), or any other desirable plant species or commodities within the target area evaluated and reported? Were these effects compared to the untreated control or check plots? Were the following characteristics addressed as appropriate?

- Stand. Were crop stand counts, reported as percentage of untreated control crop stands, submitted to support pesticides applied prior to crop emergence?

- Vigor. Were crop vigor (or stunt) ratings or measurements (plant height, weight, diameter, or length) in treated areas compared to plants in the check plots in which commercially acceptable levels of pest control are maintained?

- Planting depths. Was a range of planting depths within the range recommended for the crop included in preliminary studies with preplant and preemergence (to crop) applications? Were any effects of varying planting depths on the incidence of crop injury that might be encountered under commercial use conditions reported?

- Lodging. Were the effects of pesticides on lodging of target area crops such as soybean, wheat, corn, sorghum, rice or sugarcane indicated? Were the observed percentage of treated plants affected and the severity or approximate degree of angle of lodging in treated plots compared to that in weed-free check plots?

- Phytotoxicity. Were evaluations of visible symptoms of pesticide injury (such as discoloration, malformations, desiccation, defoliation, or death) to crop plants at least visually assessed and reported? Were these symptoms or signs compared to results in check plants untreated with the pesticide in question? If a phytotoxicity rating system was used, was it provided?

- Development. Were effects of pesticides on plant development (such as delayed emergence, prolonged vegetative growth, delayed or decreased flowering or fruit set, or delayed maturation) reported? If such effects were outgrown by or before the usual harvest date, was such recovery reported?

- Yields. Were effects of pesticides on yields reported? Yield data can confirm that there are no lasting detrimental effects on the desirable target area plants due to the pesticide application. Yield data may also be used to evaluate benefits derived from the application.